REMARKS/ARGUMENTS

Applicant would like to thank the Examiner for the careful consideration given the present application. The application has been carefully reviewed in light of the Office Action, and amended as deemed appropriate to place the application into condition for allowance.

Specifically, by this amendment claims 13 and 15 have been amended. No claims have been cancelled and no new claims have been added to the application. Accordingly, claims 13-18 are pending in the application. No new matter has been added.

In the prior Office Action, the Examiner withdrew the rejections previously asserted under 35 U.S.C. §102 and §103 in view of Nielsen et al., U.S. Pat. No. 5,716,558. However, the Examiner rejected the claims on new grounds. Specifically, the Examiner:

- rejected claim 15 under 35 U.S.C. §112, second paragraph, as being indefinite;

- rejected claims 13-15, 17 and 18 under 35 U.S.C. §103(a) as being unpatentable over the English abstract of Miyagawa et al., JP 07-196840, in view of Ravve et al., U.S. Pat. No. 3,323,946;

- rejected claim 16 under 35 U.S.C. §103(a) as being upatentable over the English abstract of Miyagawa et al. in view of Ravve et al. further in view of Barstow et al., U.S. Pat. 5,001,224; and

- rejected claims 13 and 15-18 on nonstatutory double patenting grounds.

In view of the amendments made to claims 13 and 15 herein, and in view of the arguments set forth below, applicant respectfully request reconsideration of the claim rejections.

With respect to the rejection of claim 15 under 35 U.S.C. §112, second paragraph, the Examiner noted that there was insufficient antecedent basis for the limitation "the reducing step". By this amendment, claim 15 has been amended to substitute "the milling step" for "the reducing step". There is adequate antecedent basis for "the milling step" (see claim 13, from which claim 15 depends). In view of the amendment to claim 15, reconsideration of the claim rejection is requested.

With respect to the rejection of claims 13-15, 17 and 18 under 35 U.S.C. §103(a), the Examiner noted that the English abstract of Miyagawa et al. discloses a method:

> To obtain expanded polymer particles having a controlled content of carbon dioxide by removing the residual volatile matter from a polymer by bringing the polymer into contact with carbon dioxide in a nearly supercritical or critical state.

Specifically, in accordance with the method disclosed in the English abstract of Miyagawa et al.:

> A polymer containing 1-30 pts.wt. carbon dioxide per 100 pts.wt. polymer is produced by feeding a powdery, bead-like or pelletized polystyrene polymer having a residual volatile matter concentration of 300ppm or above, or a liquid composition or the like containing a polystyrene polymer having a residual volatile matter concentration of 3000-5000ppm into an extractor, pouring a lower hydrocarbon compound, an alcohol or a mixture thereof into the extractor, blowing carbon dioxide into the mixture, keeping the temperature in the extractor at about 150° and the pressure at 50-500kg/cm2.G, and keeping the whole system for 4hr in this state. A die is set on the polymer exit of the extractor or another tank to extrude the polymer melt through this die into a cooled pressurized solution in which the polymer is not soluble at 0-90°C and a pressure of 5-100kg/cm2.G to form a rod. The rod is cut into pieces of a specified length, separated, recovered from the cooled solution, and dried.
>
> (underlined emphasis added)

The Examiner cites Ravve et al. (col. 8, lines 12-21) for the proposition that solid particles (e.g., comprising a polymer) can be obtained via milling. The Examiner thus reasons that it would have been obvious to one having ordinary skill in the art at the

time of applicant's invention to mill a polymer product of Miyagawa et al. as in Ravve et al. and thereby arrive at applicant's method as claimed. Applicant respectfully disagrees.

Claim 13 of the present application, as amended herein, claims:

> A method of producing solid particles comprising the steps of:
> providing a load stock comprising:
> an excipient that is a solid at 25° C. and 1 atmosphere pressure; and
> optionally, a biologically active substance;
> contacting the load stock with a supercritical fluid in a pressure vessel to form a melt;
> **releasing the pressure within the pressure vessel to transform the melt <u>in the pressure vessel</u> into a solid porous mass** that is cooled to a temperature below 25° C.; and
> milling the solid porous mass to obtain solid particles.
>
> (bold, underlined emphasis added)

The English abstract of Miyagawa et al. does not teach releasing the pressure within the pressure vessel to transform the melt <u>in the pressure vessel</u> into a solid porous mass. On the contrary, the English abstract of Miyagawa et al. teaches extruding the melt from the pressure vessel through a die into a cooled <u>pressurized solution</u> in which the polymer is not soluble to form a rod. The goal of Miyagawa et al. is to form a rod of polymer having compressed carbon dioxide trapped or entrained therein. This rod, which can be cut into pieces of a specified length, contains carbon dioxide and thus when heated can be used to form expanded polymer foam (e.g., a product similar to STYROFOAM). In contrast to what is taught in the English abstract of Miyagawa et al., applicant's process forms a solid porous mass <u>in the pressure vessel</u>. The pressure is released in the pressure vessel, allowing the carbon dioxide to expand and thereby form a porous (foamed) product <u>in the pressure vessel</u>. The melt is not extruded through a die from the pressure vessel into a pressurized solution as in Miyagawa et al. to form a rod containing compressed carbon dioxide.

Applicant further notes that milling the material according to Miyagawa et al. would be counter-productive to the purpose of that invention. The goal of Miyagawa et

al. is to produce polymer particles that can later be heated to create expanded polymer foam. Milling such polymer particles to a very small particle size (e.g., < 500 μm) would very likely release the carbon dioxide entrained therein, making it highly unlikely that one would obtain expanded polymer foam upon heating the milled material. In contrast to Miyagawa et al., the carbon dioxide in the porous solid mass obtained according to applicant's invention has already expanded into a gas (or converted into solid phase "dry ice") upon reduction of the pressure within the vessel. The goal is not to obtain particles containing compressed carbon dioxide. The goal is to obtain a porous solid mass that can be milled to obtain particles having a very small size. Ravve et al. clearly cannot be relied upon to cure the defects in the teachings of Miyagawa et al. as applied against applicant's claims.

Claims 14, 15, 17 and 18 of the present application depend from claim 13 and are thus patentable over Miyagawa et al. and Ravve et al. for the reasons claim 13 is patentable over such references. Furthermore, with respect to claim 14, applicant notes that neither Ravve et al. nor Miyagawa et al. teach milling a solid porous mass before the temperature of the solid porous mass is permitted to rise to or above 25° C. Ravve et al. is the only reference of record that discusses milling. And Ravve et al. merely teaches milling solids used in a coating composition to a particle size of 12 microns or less (e.g., using a ball mill or a three-roll mill). There is no teaching in Ravve et al. as to the milling conditions claimed in claim 14 (i.e., before the temperature of the solid porous mass is permitted to rise to or above 25° C.). Furthermore, the material that is milled according to Ravve et al. is not a porous solid mass recovered from a pressure vessel from which the pressure was rapidly reduced. The reference is simply inapposite and cannot be combined with Miyagawa et al. to read on applicant's invention.

Applicant respectfully submits that the Examiner's rejection of claim 16 under 35 U.S.C. §103(a) is also improper. Claim 16 depends from claim 13. As noted above, the Examiner's rejection of claim 13 is flawed for the reasons set forth above. Miyagawa et al. and Ravve et al. simply cannot be combined in any way to establish a *prima facie* case of obviousness as to applicant's invention as claimed in claim 13. And Barstow et al. cannot be relied upon to cure the defects in the Examiner's base combination.

Barstow et al. teaches the use of supercritical carbon dioxide as a "reaction solvent for organic reactions" including reactions for synthesizing polypeptides. Barstow et al. does not teach contacting an excipient material such as defined in claim 16 with a supercritical carbon dioxide in a pressure vessel to form a melt, and then releasing the pressure within the pressure vessel to transform the melt in the pressure vessel into a solid porous mass that is cooled to a temperature below 25° C. as claimed. Because Barstow cannot be relied upon to cure the defects in the base rejection, reconsideration of the rejection of claim 16 is thus respectfully requested.

Finally, the Examiner rejected claims 13 and 15-18 on nonstatutory obviousnbess-type double patenting grounds as being unpatentable over claims 1 4-7 of Shekunov et al., U.S. Pat. 6,986,846. The Examiner contends that the invention as claimed herein is the same as the invention claimed in claims 1 and 4-7 of Shekunov et al. '846 except for an additional milling step. However, the Examiner is clearly mistaken. Claim 1 of Shekunov et al. '846 claims:

> A method of forming particles, the method comprising:
> mixing a load material with a first flow of a supercritical fluid in a first mixing chamber having a primary mixing device disposed therein to form a melt;
> transferring the melt from the first mixing chamber to a second mixing chamber having a secondary mixing device disposed therein;
> mixing the melt with a second flow of the supercritical fluid in the second mixing chamber to form a lower viscosity melt; and
> expanding the lower viscosity melt across a pressure drop into an expansion chamber that is at a pressure below the critical pressure of the supercritical fluid to convert the supercritical fluid to a gas and thereby precipitate the load material in the form of particles.
>
> (underlined emphasis added)

Applicant's invention as claimed in claim 13 requires a step of:

> releasing the pressure within the pressure vessel to transform the melt in the pressure vessel into a solid porous mass that is cooled to a temperature below 25° C.

This step is simply not possible in accordance with Shekunov et al. '846, which requires expanding the material across a pressure drop into an expansion chamber. The two inventions are completely different. Accordingly, the nonstatutory obviousness-type double patenting rejection is improper and should be withdrawn.

In light of the foregoing, it is respectfully submitted that the present application is in a condition for allowance and notice to that effect is hereby requested. If it is determined that the application is not in a condition for allowance, the Examiner is invited to initiate a telephone interview with the undersigned attorney to expedite prosecution of the present application.

If there are any additional fees resulting from this communication, please charge same to our Deposit Account No. 18-0160, our Order No. FER-14670.001.002.

Respectfully submitted,

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